

OCT - 5 2000

K002069

510 (K) Summary of Safety and Effectiveness

Company Name:	Spinal Innovations 7850 Stage Hills Blvd. Suite 105 Bartlett, TN 38133 (901) 373-8855
510(k) Contact:	Ken Russell Vice President of Regulatory And Clinical Affairs (901) 373-8855
Trade Name:	Spinal Innovations Ascend™ Spinal Fixation System
Common Name:	Hook, Rod and Screw Spinal Fixation System
Classification:	888.3050 Spinal Interlaminar Fixation Orthosis
Device Product Code:	97 KWP and MNH
Predicate Devices:	Depuy Motech MOSS Miami System Medtronic Sofamor Danek Multi Axial Screw Medtronic Sofamor Danek Multi TSRH Spinal System Wright Medical Technology Wrightlock™ Spinal System Wright Medical Technology Versalok™ Low Back Fixation System

Device Description

The Spinal Innovations Ascend™ Spinal Fixation System is a temporary implant system used to correct spinal deformity and facilitate the biological process of spinal fusion. This system is intended for posterior use in the thoracic, lumbar and sacral areas of the spine. Implants of this system consist of hooks and/or screws connected to rods and are intended to be removed after solid fusion has occurred. This system includes fixed and polyaxial screws of varying diameters and lengths and hooks in varying designs.

Intended Use

The Spinal Innovations Ascend™ Spinal Fixation System, when used as a pedicle screw fixation system, is indicated for use in patients: a) having severe spondylolisthesis (Grade 3 and 4) at the L5-S1 joint; b) who are receiving fusion using autogenous graft only; c) who are having the device fixed or attached to the lumbar or sacral spine; and d) who are having the device removed after the development of a solid fusion mass. When used for this indication, the fusion mass may not go above the L5-S1 joint, the levels of pedicle screw fixation may span from L3 to the sacrum.

The Spinal Innovations Ascend™ Spinal Fixation System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as a hook and sacral screw system (other than pedicle screw fixation system for high grade spondylolisthesis), the Spinal Innovations Ascend™ Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined by chronic back pain of discogenic origin with the degeneration of the disc confirmed by a history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal surgery/fusion. When used for this indication, screws of the Spinal Innovations Ascend™ Spinal Fixation System are intended for sacral/iliac attachment only. Hooks of the system are intended for posterior thoracic and/or lumbar use only. The levels of use for hook and sacral screw fixation of this system are T1 to the sacrum.

Testing

Biomechanical testing demonstrated that the components of the Spinal Innovations Ascend™ Spinal Fixation System exhibit equivalent mechanical performance, compared to predicate devices.

Basis for Substantial Equivalence

The Spinal Innovations Ascend™ Spinal Fixation System is substantially equivalent in material, design and function to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT - 5 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kenneth Russell
Vice President, Regulatory Affairs
Spinal Innovations, LLC
7850 Stage Hill Boulevard
Suite 105
Bartlett, Tennessee 38133

Re: K002069

Trade Name: Ascend™ Spinal System
Regulatory Class: Class II
Product Code: KWP, MNH, MNI
Dated: July 6, 2000
Received: July 7, 2000

Dear Mr. Russell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Mark N. Melanson
Celia M. Witten, Ph.D., M.D.

Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number 1C002069

Device Name: Spinal Innovations Ascend™ Spinal Fixation System.

Indications for Use:

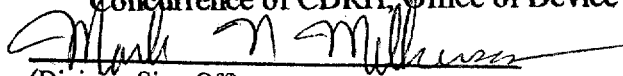
The Spinal Innovations Ascend™ Spinal Fixation System, when used as a pedicle screw fixation system, is indicated for use in patients: a) having severe spondylolisthesis (Grade 3 and 4) at the L5-S1 joint; b) who are receiving fusion using autogenous graft only; c) who are having the device fixed or attached to the lumbar or sacral spine; and d) who are having the device removed after the development of a solid fusion mass. When used for this indication, the fusion mass may not go above the L5-S1 joint, the levels of pedicle screw fixation may span from L3 to the sacrum.

The Spinal Innovations Ascend™ Spinal Fixation System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as a hook and sacral screw system (other than pedicle screw fixation system for high grade spondylolisthesis), the Spinal Innovations Ascend™ Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined by chronic back pain of discogenic origin with the degeneration of the disc confirmed by a history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal surgery/fusion. When used for this indication, screws of the Spinal Innovations Ascend™ Spinal Fixation System are intended for sacral/iliac attachment only. Hooks and transverse connectors of the system are intended for posterior thoracic and/or lumbar use only. The levels of use for hook and sacral screw fixation of this system are T1 to the sacrum.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

Prescription Use _____
 510(k) Number K002069
 (per 21 CFR 801.109) OR

Over-The-Counter Use _____

(Optional Format 1-2-96)